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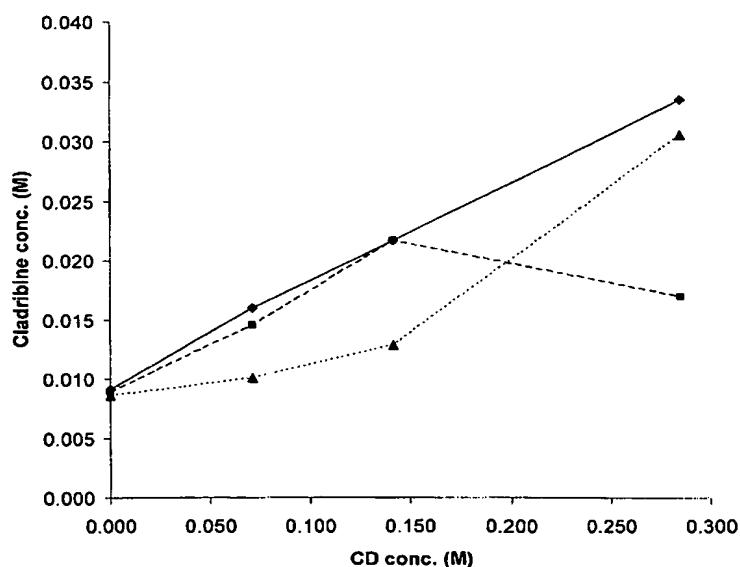
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[Continued on next page]

(54) Title: **CLADRIBINE FORMULATIONS FOR IMPROVED ORAL AND TRANSMUCOSAL DELIVERY**



(57) Abstract: Provided are compositions of cladribine and cyclodextrin which are especially suited for the oral and buccal administration of cladribine.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

International Application No

T/US2004/009384

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/20 A61K47/48 A61K31/52 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 194 395 B1 (NAEFF RAINER ET AL) 27 February 2001 (2001-02-27) cited in the application the whole document	1-61
A	US 4 727 064 A (PITHA JOSEF) 23 February 1988 (1988-02-23) the whole document	1-61
A	US 4 870 060 A (MUELLER BERND W W) 26 September 1989 (1989-09-26) the whole document	1-61

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \* & \* document member of the same patent family

Date of the actual completion of the international search

2 December 2004

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/009384

### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  

Although claims 13-37 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6194395	B1	27-02-2001	NONE
US 4727064	A	23-02-1988	US 4596795 A 24-06-1986
US 4870060	A	26-09-1989	AT 124055 T 15-07-1995
			AT 159954 T 15-11-1997
			AU 583599 B2 04-05-1989
			AU 5476086 A 16-10-1986
			CA 1300130 C 05-05-1992
			CY 1918 A 07-03-1997
			DE 3650336 D1 27-07-1995
			DE 3650655 D1 11-12-1997
			DE 3650655 T2 12-03-1998
			DK 121486 A 16-09-1986
			DK 200201960 A 10-02-2003
			EP 0197571 A2 15-10-1986
			EP 0636634 A1 01-02-1995
			ES 8705899 A1 01-08-1987
			FI 861064 A ,B, 16-09-1986
			FI 86507 B 29-05-1992
			GR 860685 A1 11-07-1986
			HK 131896 A 26-07-1996
			HU 42514 A2 28-07-1987
			HU 206381 B 28-10-1992
			IE 66673 B1 24-01-1996
			IE 80908 B1 16-06-1999
			IE 950700 L 15-09-1986
			JP 2562809 B2 11-12-1996
			JP 61275301 A 05-12-1986
			KR 9307386 B1 09-08-1993
			NO 860971 A ,B, 16-09-1986
			NZ 215350 A 29-03-1989
			PT 82186 A ,B 01-04-1986
			SG 48788 A1 18-05-1998
			US 4764604 A 16-08-1988
			ZA 8601930 A 28-10-1987